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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,821

10/21/2005

Luis Octavio Guisasola

4258-113

8347

23448

7590

06/09/2010

INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

06/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,821	Applicant(s) GUISASOLA ET AL.	
	Examiner Barbara P. Badio	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 16, 17 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 16, 17 and 24-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 19-22 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 102

3. The rejection of claims 9, 13, 18 and 23 under 35 USC 102(b) over Kim et al. (WO 96/30390) is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 103

4. The rejection of claims 12-14 and 19-22 under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022) is made moot by the cancellation of the instant claims.

5. The rejection of claims 1-8, 10, 16, 17 and 24-26 under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022) is maintained.

Applicant's argument and the declaration filed March 4, 2010 center around the isolation of the crystalline VA-2914 isopropanol hemisolvate. According to applicant, (a)

Kim may or may not have formed an isopropanol hemisolvate but such was not separated and Cook does not disclose the formation of an hemisolvate (see paragraphs 8 and 9 of the declaration), (b) Kim does not disclose the process of claim 7 because it does not employ a lower excess of Grignard reagent which allows to selectively add the aryl group without affecting any of the remaining reactive groups of the molecule (see paragraphs 10 and 11 of the declaration) and (c) with respect to claims 24-26, Kim does not teach or suggest obtaining isolated VA-2914 in the form of white crystals with a melting point of around 189°C (see paragraph 12 of the declaration). Applicant's argument was considered but not persuasive for the following reasons.

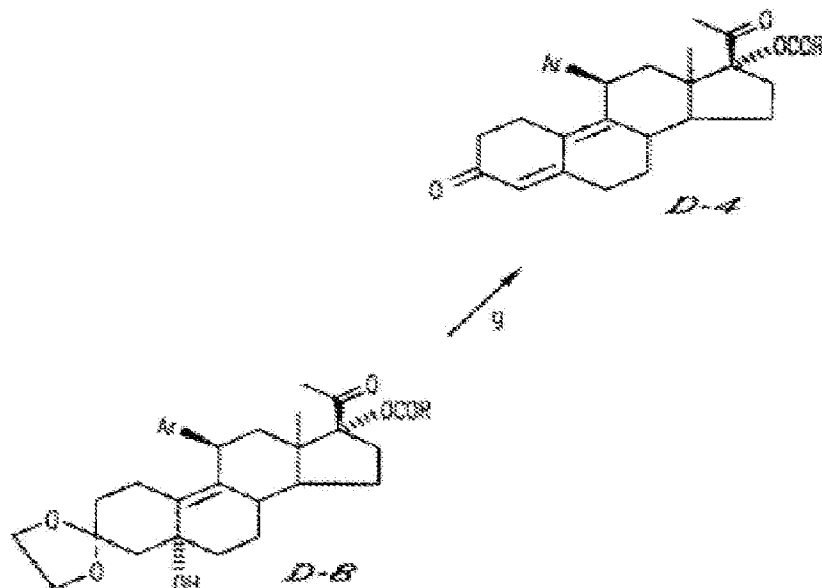
In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As indicated in previous Office Actions, the only difference between the claimed process and the process of Kim is the formation of the hemisolvate, cooling versus evaporation of solvent. However, because both cooling and evaporation of solvent are known to induce crystallization, said is not a patentable distinction. Cook was utilized for the teaching of the production of compounds of D-4 via acid hydrolysis of compounds of D-8, as recited by instant claim 7 (see below). Additionally, Cook teaches a process for purification of similar compounds wherein in the compounds are obtained in >99% purity (see the Example of Cook).

Process: As noted above, applicant's argument centers around the method via which the hemisolvate is isolated. Unlike the claimed process which involves cooling and isolating the crystalline VA-2914 isopropanol hemisolvate, Kim teaches evaporating the solvent and obtaining the solid hemisolvate. As discussed in previous Office Actions, evaporation and cooling are both means by which crystallization can be induced.

Additionally, both processes comprise the conversion of said hemisolvate into VA-2914 via recrystallization, i.e., purification, in similar solvents, i.e., an ether. Applicant is arguing unobviousness based on the purity and melting points of the end products, VA-2914. However, (a) a purity of 99.2% is not considered significantly different from that of 98.57%, i.e., it is within the margin of error that might be obtained within a laboratory and (b) a melting point of “**around**” 189°C would fall within the range of 183-185°C taught by Cook. Because, VA-2914 have a medicinal use further purification would be prima facie obvious. The claimed invention recites "comprising" and, thus, would not eliminate any additional purification.

In response to claim 7, it is noted that Cook teaches the production of similar compounds as taught by Kim and the instant invention and the reaction step:



(see Figure 4 of Cook). Thus, the acid hydrolysis of carbinol acetate with the production of VA-2914 as recited by claim 7 would have been obvious to one of ordinary skill in the art at the time of the present invention based on the teaching of Cook.

Products: Like with the process claims, applicant is arguing the purity and melting point of VA-2914 and, thus, the examiner's response is as indicated above.

Additionally, applicant seems to be arguing that because Cook teaches purification via chromatography and does not teach the production of an isopropanol hemisolvate, that the claimed product is nonobvious. However, the issue of patentability of the product does not depend on the process via which it is obtained. The issue is whether based on the teachings of the prior art, it would have been obvious to further purify the compound, VA-2914 as taught by Kim, to obtain a purer form of said compound. One motivation would be based on the fact that the art teaches a medicinal use for said compound and, thus, the skilled artisan would want to improve the purity of

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the compound to reduce any adverse effect(s) due to impurity. Because the compounds of Cook encompass that of Kim, the utilization of the purification process of Cook to obtain the compound of Kim in >99% purity as taught by Cook would have been prima facie obvious.

For these reasons and those given in the previous Office Actions, the rejection of claims 1-8, 10, 16, 17 and 24-26 under 35 USC 103(a) over Kim et al. (WO 96/30390) in view of Cook et al. (WO 99/45022) is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628